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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/646,852 | 09/22/2000 | Per Johan Lundberg | 1103326-0686 | 1116 |

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NEW YORK, NY 10036

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/646,852

Applicant(s)

LUNDBERG ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-20 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Applicant's request for reconsideration, filed on June 10, 2002, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (EP 0237200-A2).

The claimed invention refers to an oral pharmaceutical dosage form of omeprazole comprising a core coated with a membrane, process of making and method of administering said dosage form.

Makino et al. discloses pharmaceutical compositions of benzimidazole derivatives, including omeprazole, said compositions prepared by mixing the drug with basic inorganic salts and additives, including vehicles such as sucrose and cellulose, binders such as hydroxypropylcellulose and PVP, and lubricants, such as talc (See e.g., p. 8, lines 14-23).

Makino et al. teaches that the mixture can be made up into dosage forms, such as tablets and capsules and the tablets may be coated by known methods to mask the taste or to provide enteric or sustained release properties, and includes ethylcellulose among the coating agents used in the invention (See e.g., p. 8, lines 34-41). In Example 8, Makino et al. teaches that the powder used

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to coat the spherical granules contains sucrose and corn starch, which are modifying agents (See e.g., p. 14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Makino et al. to device sustained release dosage forms of omeprazole. The expected result would have been a successful dosage form of omeprazole and successful methods of manufacturing and administering said dosage form . Because of the teachings of Makino et al., that sustained release pharmaceutical compositions of omeprazole exhibit excellent gastric anti-secretory and anti-ulcer activities, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

3. Claims 1, 3-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergstrand et al.

Bergstrand et al. provides multiple unit tableted dosage forms of omeprazole, said dosage forms comprising a core material comprising seeds layered with a mixture of the active substance with binders, fillers, disintegrating agents, alkaline additives or other pharmaceutical ingredients, and a separating layer applied to the core by coating and comprising polymers, such as ethylcellulose, and additives, such as anti-tacking agents, including talc, and silicate (See e.g., col. 3, line 64 to col. 6, line 44).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Bergstrand et al. to device sustained release dosage forms of omeprazole. The expected result would have been a successful dosage form of omeprazole and successful methods of manufacturing and administering said dosage form . Because of the teachings of Bergstrand et al., that talc increases the thickness of the membrane and improve the stability of the active substance, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments filed on June 10, 2002, have been fully considered but they have been found only partially persuasive.

5. Applicant argues that the coating agents disclosed by Makino et al. include both water-soluble and water-insoluble polymers, whereas the claimed invention requires a membrane comprising a water-insoluble polymer, specifically ethylcellulose. In response to said argument, it is noted that the comprising language of the claims in the instant application allows for additional ingredients in the composition and one of ordinary skill in the art would determine the best polymeric composition in the membrane by routine experimentation.

6. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

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long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, Makino et al. specifically includes ethylcellulose among the coating agents used in a dosage form of omeprazole (See e.g., p. 8, lines 34-41). Therefore, it would have been obvious to one of ordinary skill in the art to apply the teachings of Makino et al. to device a dosage form of omeprazole comprising an ethylcellulose coating.

7. In response to Applicant's argument, that the examples in the reference are directed to enteric coatings, it is noted that the reference provides the general teaching that dosage forms of omeprazole may comprise an ethylcellulose coating. Delayed release and the differences between delayed and sustained release, which are argued by Applicant, are not recited in the pending claims. Furthermore, ethylcellulose inherently provides delayed release.

8. Applicant's argument regarding the teachings of Yanai et al. have been found persuasive, since Yanai et al. teaches a coating comprising a water-soluble polymer. Accordingly, the 35 U.S.C. 103(a) rejection of claims 1, 3-20 and 23-26 over Yanai et al. in view of Bergstrand et al. of the previous Office action is withdrawn. However, the teachings of Bergstrand et al. are still considered relevant to the claimed invention.

Conclusion

Claims 1, 3-20 and 23-26 stand rejected.

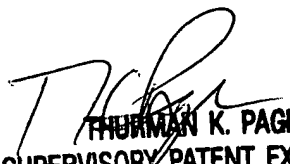
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

July 2, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600